

# 2011 Military Health System Conference

## Research Advances In Medical Care For Polytrauma Injuries And Blast Injuries

*The Quadruple Aim: Learning & Growth, Readiness, Experience of Care*

COL Dallas Hack MD

25 January 2011



US Army Medical Research and Materiel Command  
Combat Casualty Care Research Program

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# Problems/Threats



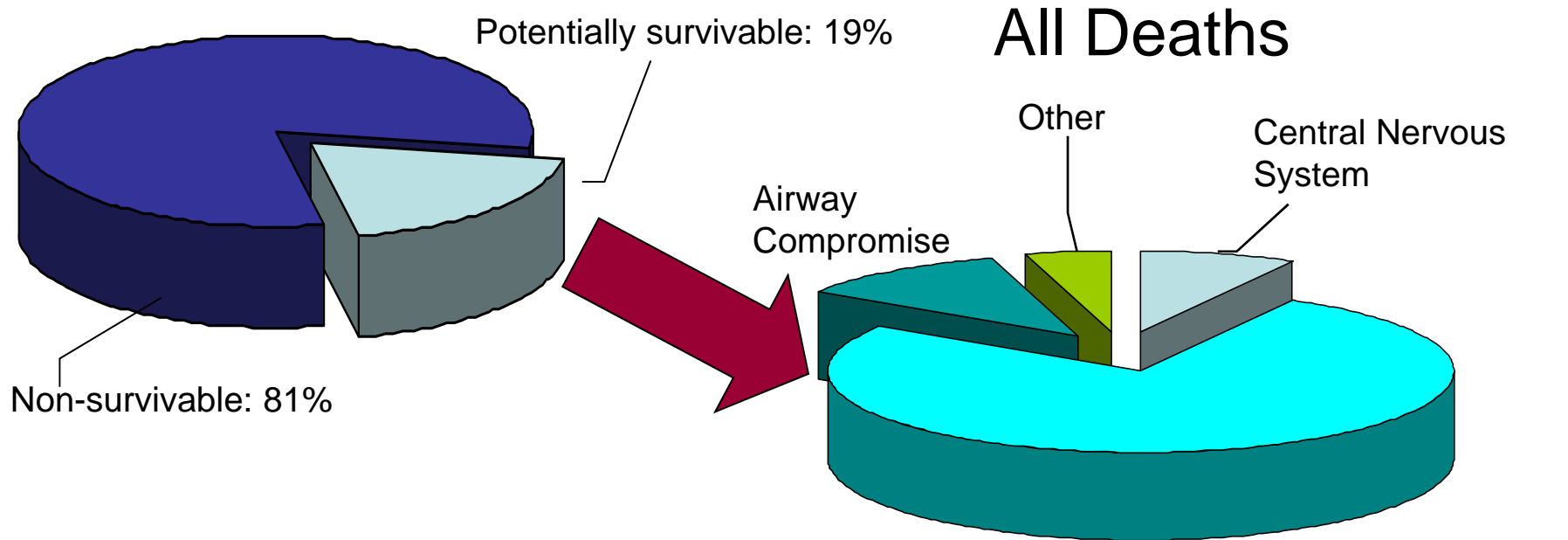
- 19% of Combat Deaths are considered preventable, major cause is uncontrolled hemorrhage\*
- 42,167 battle injuries as of 21 January 2011\*\*
  - 82% of battle injured have an extremity injury
  - Avg 2.3 per injured Soldier (Owens, JTrauma, 2007)
  - Accounts for 64% of disability (\$1.1B) (Masini, 2008)
- As of 30 Sep 2010, 195,542 Servicemembers suffered a Traumatic Brain Injury since 9/11\*\*\*, 150,222 of which are classified as mild

\*(Kelly et al., J Trauma, Feb 2008)

\*\*<http://www.defense.gov/news/casualty.pdf>, accessed 21 Jan 2011

\*\*\*<http://www.dvbic.org/TBI-Numbers.aspx>, accessed 17 Jan 2011

# Causes of Death on the Battlefield



### Non-survivable injuries:

- Catastrophic TBI
- Cardiac laceration / puncture
- Thoracic great vessel injury
- Intra thoracic tracheal injury
- Open pelvis

### Top cause of preventable DOW\*:

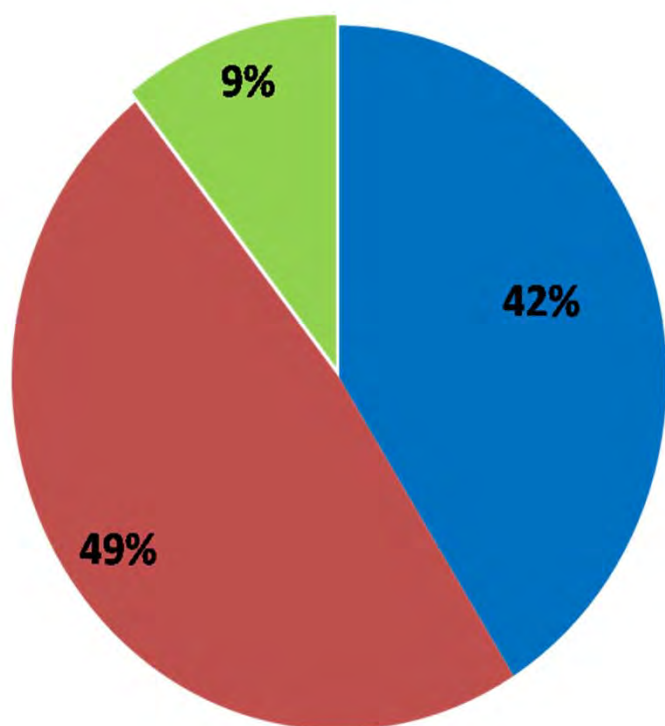
- Hemorrhage 76%
- Burn 13%
- TBI 6%
- MOF 3%
- Airway 1%

\*DOW: Died of Wounds at Role 3+

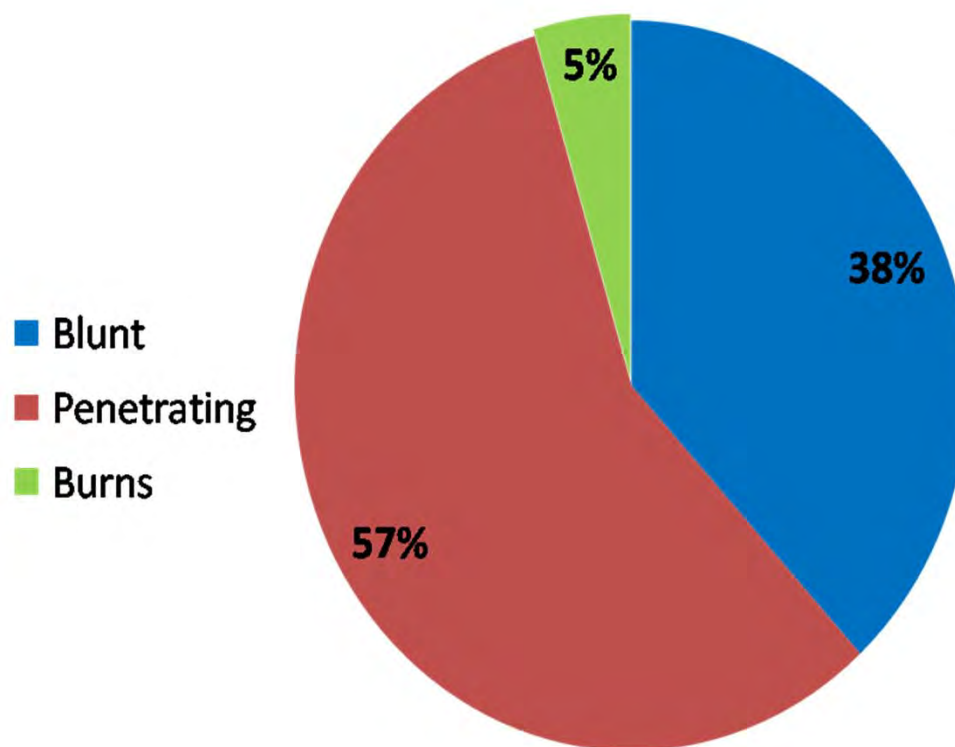
# OIF and OEF Dominant Mechanism of Injury



OIF



OEF



*1-Year's Data: Sep 08 – Aug 09*

# Combat Casualty Care “Big Problems”



- Mortality

- **Non-compressible Hemorrhage**
  - Coagulopathy
- **Compressible Hemorrhage**
  - Extremity
  - Ax/neck/groin
- Central Nervous System
- Pneumothorax
- Airway Compromise
- Deep Vein Thrombosis
- Multisystem Organ Failure
- Sepsis

- Training

- **Medic**
- **Specialty Surgeon**
- Other Providers

- Morbidity

- **Traumatic Brain Injury**
  - Mild to Severe
- Orthopedic Trauma
- Massive Soft Tissue Injury
- Burn
- Eye Trauma
- Ear Trauma
- Craniofacial Injury
- Pain Control
- Wound Infection

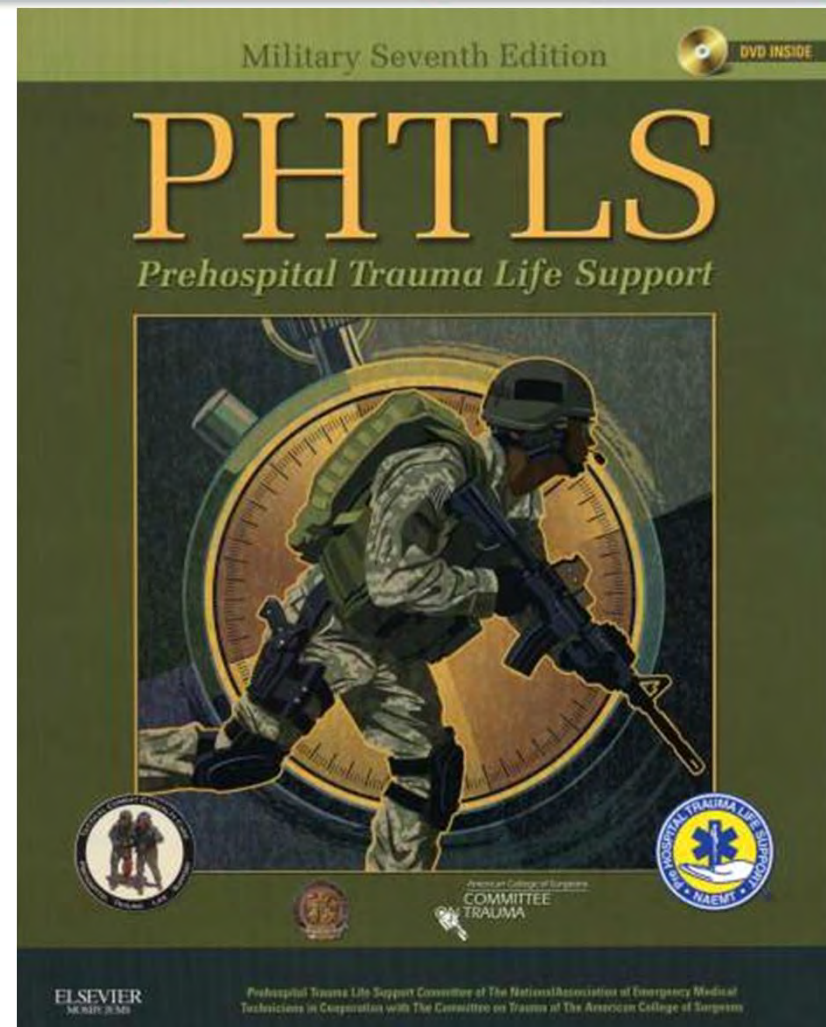


# PHTLS/Tactical Combat Casualty Care



Accepted by American College of Surgeons  
*Published in Pre-Hospital Trauma Life Support Manual (Chapters 24-35)*

- Casualty continues as combatant if able
- Early use of tourniquets
- Hypotensive Resuscitation
- Intraosseous access if IV difficult
- PO fluids OK in combat casualties
- Hextend instead of Hespan
- Combat Gauze & Woundstat dressings
- PO meds (Combat Pill Pack) if able to use
  - Gatifloxacin 400 mg
  - Acetaminophen 1000mg
  - Meloxicam 15 mg
- Blood products on helicopters
- Changed oxygen guidelines for Tactical Evacuation



Seventh Edition – Now Available

# Improved Training



## Training for Combat Lifesavers (CLS) & Medics



### Core Skills - Point of Wounding Providers



CORE SKILLS	CLS	Medic
Clear an upper airway obstruction	YES	YES
Perform CPR	YES	YES
Insert a nasopharyngeal airway	YES	YES
Perform a surgical cricothyroidotomy	NO	YES
Perform a trauma casualty assessment	+/-	YES
Control bleeding using pressure dressings	YES	YES
Apply a tourniquet to control active bleeding	YES	YES
Recognize signs and symptoms of shock	YES	YES
Start an intravenous infusion	YES	YES
Perform needle chest decompression	YES	YES
Initiate an intraosseous infusion	NO	YES

CORE SKILLS	CLS	Medic
Recognize cardiac arrest / defibrillation with AED	+/-	YES
Splint extremity fractures	YES	YES
Evaluate and provide initial treatment for burns	+/-	YES
Perform initial triage of casualties	+/-	YES
Request medical evaluation	YES	YES
International Humanitarian Law / Detainee Care	NO	YES
Minor surgical procedures	NO	YES
Emergency surgical procedures	NO	YES
Blast injuries	NO	YES
Tactical combat casualty care concepts	YES	YES



# Combat Application Tourniquet® (C-A-T®)



**DESCRIPTION:** The C-A-T (patent pending) is a small and lightweight one-handed tourniquet that occludes arterial blood flow in an extremity. The C-A-T uses a Self-Adhering Band and a Friction Adaptor Buckle to fit a wide range of extremities combined with a one-handed windlass system. The windlass uses a free-moving internal band to provide true circumferential pressure to an extremity.

**REQUIREMENT:** FOC 09-06 Health Services Support b. 7 (d) – intelligent tourniquets to limit blood loss, without irreparable tissue damage



**PARTNER:** North American Rescue, Inc.

**TRANSITION:** Commercially available

**COST:** \$25.98 each

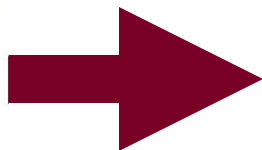
**QTY:** As of January 2009, about 2.6M C-A-Ts have been fielded.

**SCHEDULE:** Fielded. Issued one per soldier with the Individual First Aid Kit

# Soldier Training/ Improved First Aid Kit (IFAK)



- All Soldiers now trained as Combat Lifesavers during Basic Training
  - Basic casualty evaluation
  - Airway management
  - Chest injury and tension pneumothorax mgmt
  - Control bleeding
  - Request medical evacuation





# Joint Theater Trauma System (JTTS) & Joint Theater Trauma Registry (JTTR)



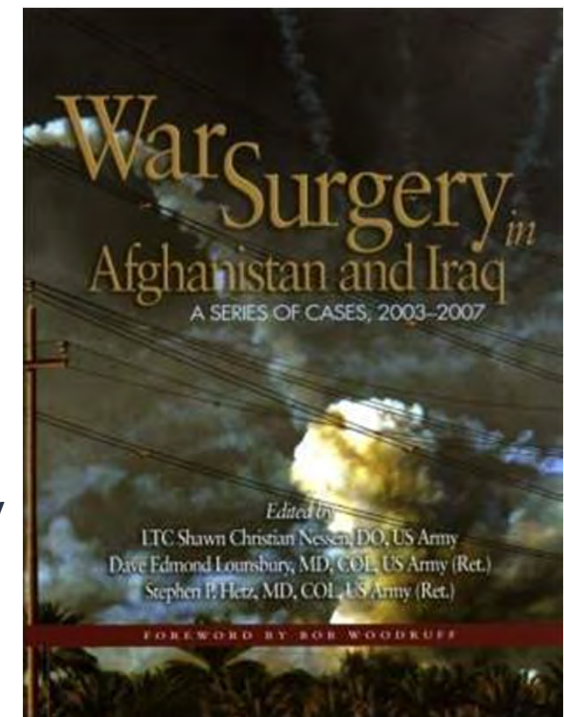
- Integrated systems approach to Combat Casualty Care
- Right patient, right place, right time, right care
- Trauma Registry
  - Real time data, 90 dedicated personnel
- Data driven method of making changes
  - Better body armor
  - Impact of helicopter evacuation times
  - Employment of Forward Surgical Teams
- Merge registry with operational data and medical record
- Training
- Research



# Joint Theater Trauma System



- World Wide Telecommunications:
  - Weekly f/u conf call with Level II+, III, IV, V and VA share lessons learned
  - Weekly Trauma Nurse Coordinators call, including all theater and LRM/CONUS
  - Monthly System-wide VTC for system issues
    - Includes VA, JPMRC, GPMRC, AMC, CENTAF, CENTCOM
  - Bi-monthly JTTS Directors conference call
- Committee on Tactical Combat Casualty Care
- Joint Forces Combat Surgical Training
- War Surgery Manual
- Clinical Practice Guidelines
- Surgeon General Policies
- Integrate clinical guidelines from the war into mandatory training



# Clinical Practice Guidelines



	<u>Reviewed</u>
1 Acoustic Trauma and Hearing Loss	February 16, 2010
2 Amputation	February 16, 2010
3 Blunt Abdominal Trauma	June 30, 2009
4 Burn Care	December 20, 2009
5 Catastrophic Care	February 16, 2010
6 Cervical Spine Evaluation	June 30, 2010
7 Compartment Syndrome (CS) and the Role of Fasciotomy in Extremity War Wounds	April 30, 2009
8 Damage Control Resuscitation at Level IIb/III Treatment Facilities	February 13, 2009
9 Emergent Resuscitative Thoracotomy	May 6, 2009
10 Fresh Whole Blood (FWB) Transfusion	January 12, 2009
11 Frozen and Deglycerolized Red Blood Cells (RBCs)	June 30, 2010
12 Hypothermia Prevention, Monitoring, and Management	June 30, 2010
13 Infection Control	February 16, 2010
14 Inhalation Injury and Toxic Industrial Chemical Exposure	November 7, 2008
15 Initial Care of Ocular and Adnexal Injuries	February 16, 2010
16 Intratheater Transfer and Transport of Level II and III Critical Care Trauma Patients	November 19, 2008
17 Management of Patients with Severe Head Trauma	November 23, 2010
18 Management of Patients with Severe Head Trauma	June 30, 2010
19 Management of War Wounds	February 16, 2010
20 Nutrition	February 16, 2010
21 Pelvic Fracture Care	June 30, 2010
22 Post-Splenectomy Vaccination	June 30, 2010
23 Prevention of Deep Venous Thrombosis (DVT)	November 21, 2008
24 Spine Injury Surgical Management and Transport	July 9, 2010
25 Trauma Airway Management	June 30, 2010
26 Urologic Trauma Management	June 30, 2010
27 Use of Electronic Clinical Documentation in the CENTCOM AOR	June 30, 2010
28 Use of Trauma Flow Sheets	December 1, 2008
29 Ventilator Associated Pneumonia -	February 16, 2010
30 Vascular Injury	November 7, 2008

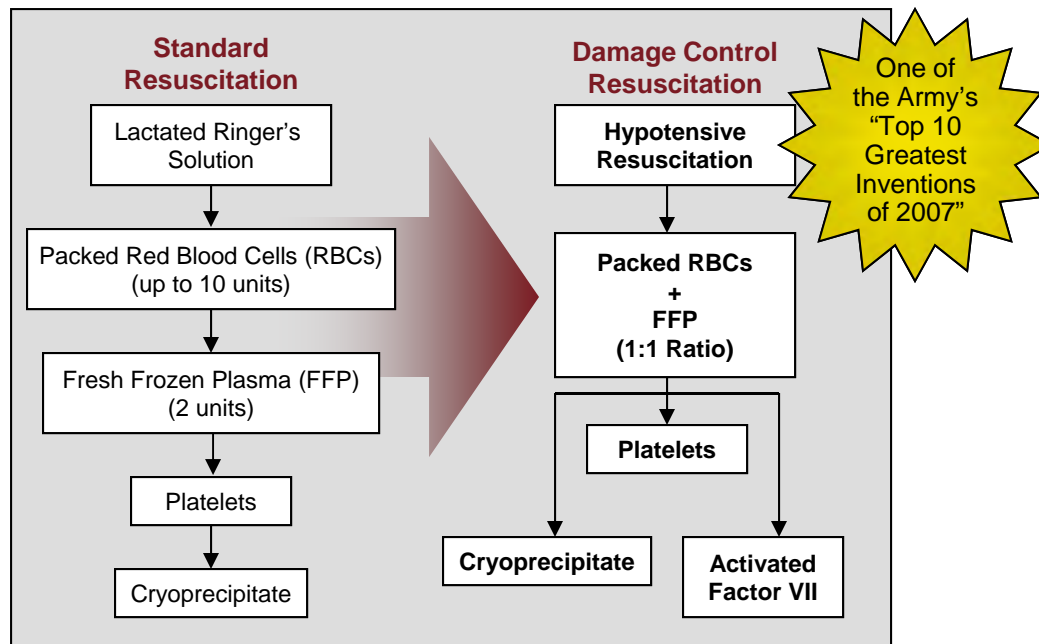
**Source:** <http://www.usaisr.amedd.army.mil/cpgs.html>  
2011 MHS Conference

# Damage Control Resuscitation for Non-Compressible Hemorrhage



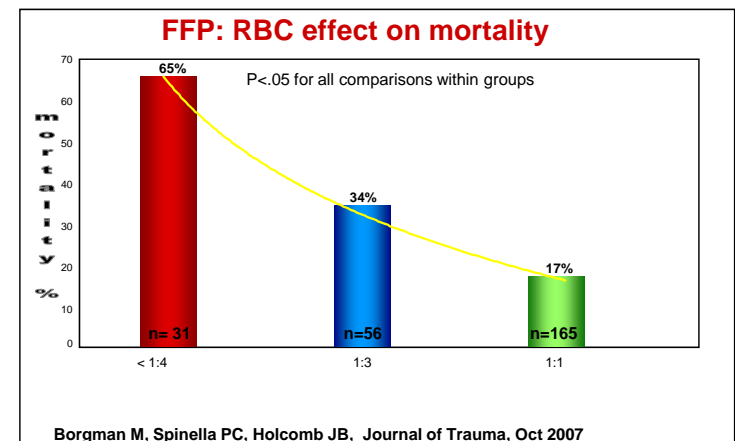
**DESCRIPTION:** Medical practice guidelines are provided for applying existing products/methods singly or in combination to stop bleeding and restore normal metabolism of the combat casualty.

**REQUIREMENT:** FOC 09-06 Health Services Support 7 (d) Stabilize Casualty – management of hemorrhage, replacement of fluids, replacement of blood components, and stabilization of vital functions



## Damage Control Resuscitation – Greater use of plasma

Damage control resuscitation is structured intervention to treat the most severely injured casualties at greatest risk of dying.



**TRANSITION:** Forward medical treatment facilities

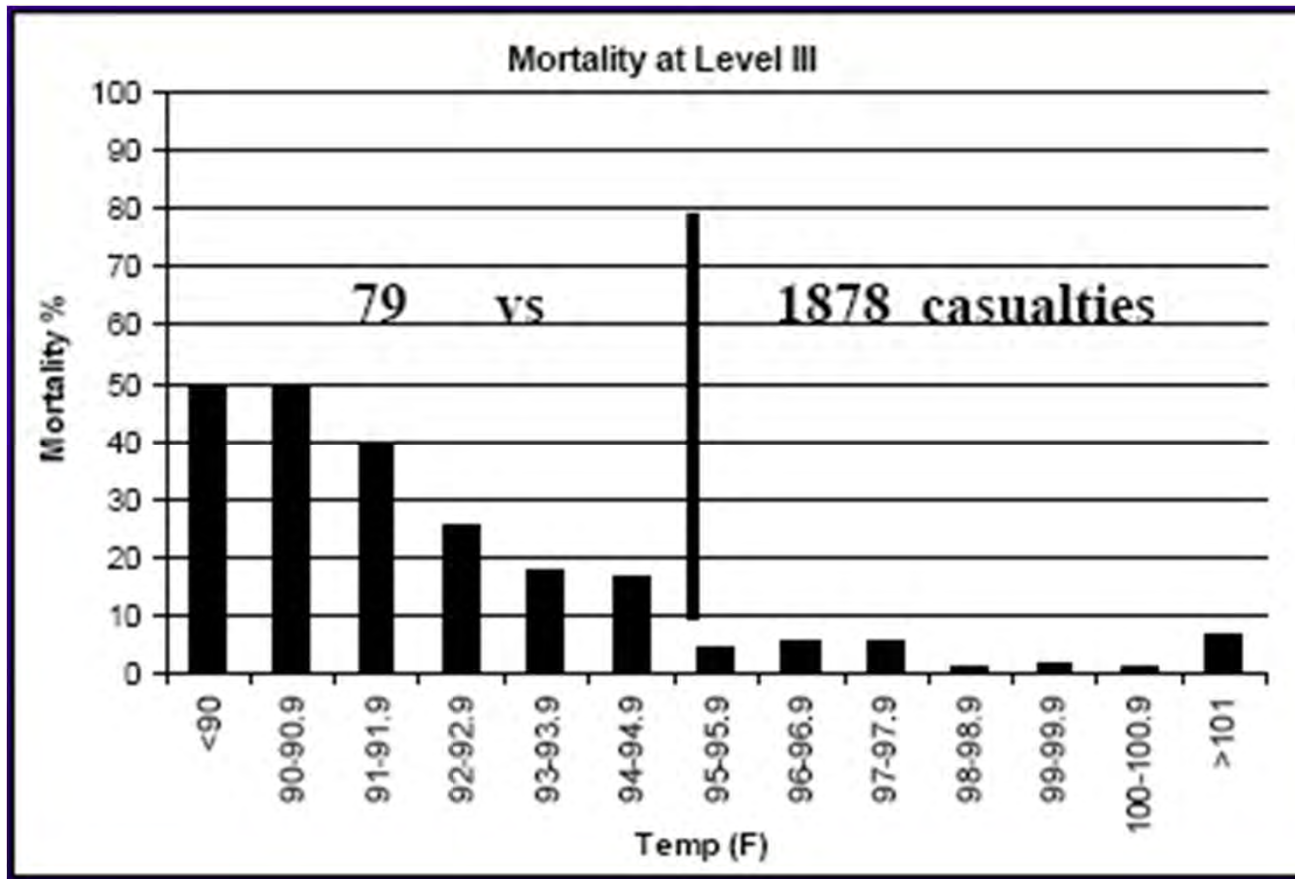
**COST:** None.

**QTY:** N/A

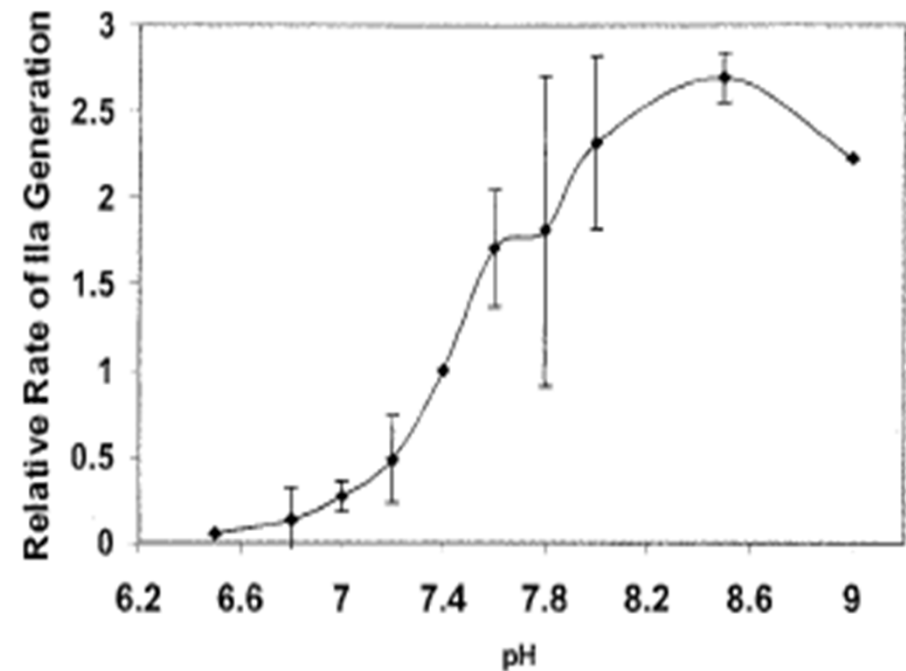
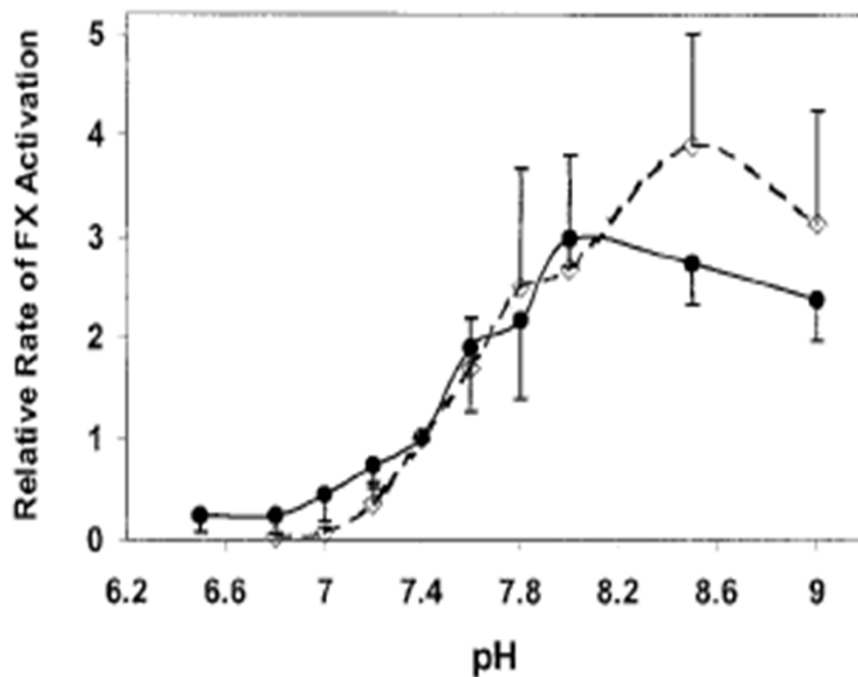
**SCHEDULE:** Fielded via ALARACT, Optimal Resuscitation of Severely Injured Soldiers, January 2007.



# Hypothermia Impact



# Acidosis Effect



- Activity of the tissue factor/factor VIIa complex decreases 55% and prothrombinase complex declines by 70% as pH declines from 7.4 to 7.030
- Plasma clotting times prolong as pH is reduced

# Coagulopathy of Trauma



- Syndrome of non-surgical bleeding from mucosal lesions, serosal surfaces, wound and vascular access sites associated with serious injury
- INR  $> 1.5$  (reliably predicts those casualties who will require massive transfusion)
- Seen in most severely injured upon admission to ED
  - Coagulopathy correlated with ISS
- Also associated with:
  - Hypothermia (temp  $\leq 35^{\circ}\text{C}$ )
  - Acidosis (pH  $< 7.2$  or BD  $\geq 6$ )
  - Hemodilution
- “Trauma-induced coagulopathy can develop in 24.4% of patients independent of acidosis and hypothermia but secondary to trauma by itself” – *J Trauma*, Aug 08, p272

# Dried Plasma



## Description

- Dried Plasma (DP) is fresh frozen plasma (FFP, standard of care) that has been dehydrated. DP is less temperature sensitive & reconstitutes more quickly than FFP
- DP will augment FFP use by allowing use closer to point of injury & earlier in the treatment regime. There is a potential to reduce mortality of salvageable hemorrhage deaths by 2/3 with improved intravascular hemostatic agents, like plasma.



## Benefits

- Life-saving technology for massive blood loss on the battlefield.
- Reduce the logistical footprint by reducing the refrigeration requirements associated with fresh frozen plasma.
- Extended shelf-life and temperature stability.
- Can be used in far-forward medical treatment facilities (combat support hospital and forward surgical teams) for casualty management, by the physician assistant or surgeon.

## Key Participants

- USAMMDA
- ONR
- Industry
- US Army Institute of Surgical Research
- Combat Casualty Care Research Program
- AMEDDC&S

# Cryo-Preserved Platelets (Frozen Platelets)



## Description

Platelets are a key element in normal blood clotting after injury or surgical incision. The current blood-banked platelet product can be stored for only 5 days and is generally not available on the battlefield. Platelets continue to be absent in Operation Enduring Freedom but fresh whole blood and deployment of platelet apheresis have been used to fill the gap in Operation Iraqi Freedom. A platelet substitute will fill the current gap in effective medical management of hemorrhage at the combat support hospital.



## Benefits

- The functional activity of this blood product is similar to native platelets with regard to the clotting function.
- Key attributes of this product are battlefield availability, potentially prolonged shelf-life, and greatly enhanced temperature stability if the lyophilized preparation is successful.
- Greatly enhanced shelf-life at ambient temperatures and the capability to be deployed far forward, including the forward surgical team and perhaps the battalion aid station for casualty management

## Key Participants

- AMEDDC&S
- USAISR
- Combat Casualty Care Research Program
- USAMRAA
- Regulatory Affairs, USAMMDA
- Industry



# Field Portable Oxygen Generator Ceramic and RVPS



## Description

The logistical burden of resupply and refill of oxygen cylinders will be eliminated.

**RVPS:** The generator replaces the standard “D” cylinder for patient care and transport and yields increased efficiency and reduced size and weight.

**Ceramic:** Uses a minimum of mechanical parts; instead it uses a thin, hot ceramic membrane that has a voltage applied to it. It is insensitive to environmental conditions.



Ceramic Oxygen Generator



Rotary Valve Pressure Swing (RVPS) Oxygen Generator

## Benefits

The generation of oxygen where it is needed reduces the logistical requirements for the transport of oxygen cylinders to and within the operational theater.

**Ceramic Oxygen Generator** uses a metal reinforced composite, thin-film ceramic membrane to generate oxygen. Producing 1 liter of oxygen requires 30 watts of electricity. The device will be battery powered and weigh only 10 pounds.

**RVPS** is a smaller, more efficient product and will reduce the logistical burden of the oxygen generator for forward-deployed medical assets for use in single-patient care and transport.

## Key Participants

- USAMMDA
- Industry
- US Army Institute of Surgical Research
- Combat Casualty Care Research Program
- AMEDDC&S



# Noise Immune Stethoscope



## Description

The noise immune stethoscope can be used in high-noise environments. The new stethoscope uses a traditional acoustic listening mode with the addition of ultrasound-based technology that is “noise immune.” Current research is assessing the utility and durability of the new stethoscope under field conditions and in patients with cardiopulmonary pathology.



## Benefits

- The ability to perform auscultation in the field environment or during evacuation, whether by air or ground ambulance.
- A stethoscope that can be used to listen to heart and breath sounds in the challenging environment
- The ability for military medical personnel to evaluate and treat patients under the most difficult environmental conditions.
- Dramatically improved diagnostic ability of medical personnel in both military and civilian settings.

## Key Participants

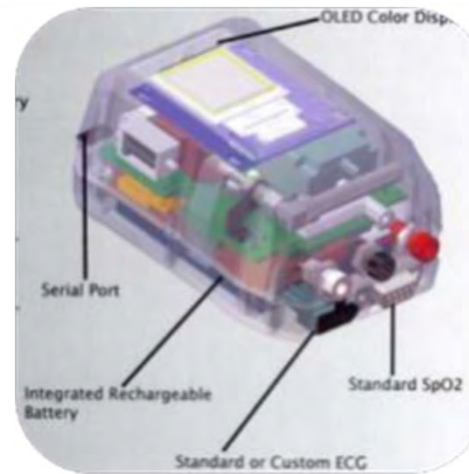
- USAARL
- USAMMDA
- Combat Casualty Care Research Program
- AMEDDC&S
- USAMRAA

# Wireless Vital Signs Monitor



## Description

This device is a wireless vital signs monitor that transmits sensor information from patients to a smart monitor worn by a medic. This device includes smart monitoring software to predict patient trends. This is a Wi-Fi device that will work with other Wi-Fi monitors or laptops. It is intended for use from Battalion Aid Stations through to the CSH level, and can be used during transport to Level IV facilities.



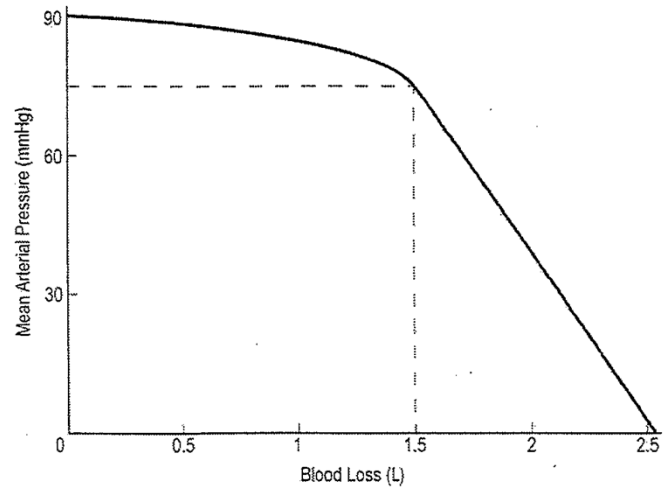
## Benefits

- Allows medical personnel to monitor numerous casualties simultaneously.
- Assists in triaging casualties by constantly monitoring their vital signs and alerting medical personnel of critical physiological changes.
- Has both military and commercial applications.
- Technical enhancements include wireless modules for frequency spectrum selection for communication, wireless ECG and improved embedded processing power while maintaining the small product footprint.

## Key Participants

- Industry
- USAISR
- Combat Casualty Care Research Program
- AMEDDC&S
- USAMRAA
- Regulatory Affairs, USAMMA

# Early Detection of Significant Blood Loss



**Figure 1.** A graphic approximation of the pressure-volume relationship of the circulation in healthy adult trauma patients with a circulating blood volume of 5 L.<sup>6a</sup>





# Medical Care During Transport



- Extended Evacuation Times
- Pre-hospital Care:
  - Noisy, chaotic, dirty

**C:** Control Hemorrhage: continually reassess tourniquets and hemostatic dressings for rebleeding. Administer fluid only for signs of profound hypotension or mental status changes.

**B:** Identify and treat tension pneumothorax: Especially important in at-risk patients at altitude.

**A:** Control Airway if necessary: Generally, <1% of casualties need airway interventions.



- “Smart” monitoring equipment with decision-assist algorithms
- “Closed-Loop” ventilation, resuscitation, and CNS homeostasis

# Total Intravenous Anesthesia (TIVA)



## Description

Total intravenous anesthesia (TIVA) uses only IV agents without the use of inhalational agents. Drugs used are generally of short duration of action and half-life in order to reduce the risks associated with accumulation. TIVA avoids unwanted effects of inhalational agents and the need for complex apparatus.



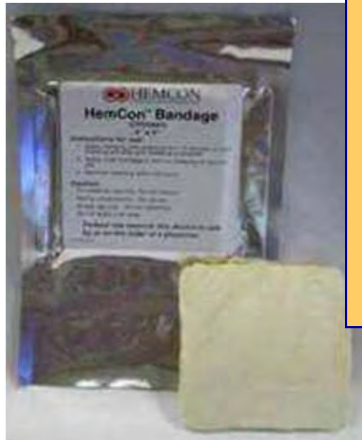
## Benefits

- Reduction of the logistical footprint.
- Ability to control sedation before induction and post-operatively.
- Decreased post-operative nausea and vomiting.
- Ability to maintain hypoxic vasoconstrictor reflex and an unrestricted access to airway.
- Oxygen conservation (particularly useful for the field).
- Reduction of waste gases and other pollution, resulting in easier OSHA compliance.

## Key Participants

- Industry
- USAMMDA
- Combat Casualty Care Research Program
- AMEDDC&S
- USAMRAA

# Post 9/11 Fielded Products Hemostasis



One of Army's  
"Top Ten  
Greatest  
Inventions  
of 2004"

**HemCon Bandage**



**QuikClot**

One of Army's "Top Ten  
Greatest Inventions of 2005"



**Combat Application Tourniquet (CAT)**



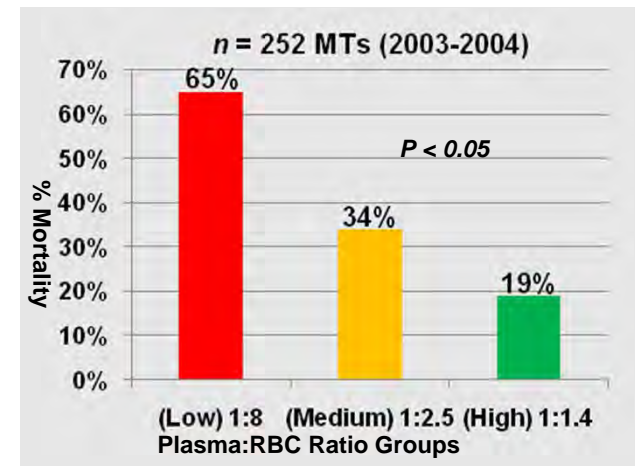
**NovoSeven Injectible Clotting Agent**

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One of Army's  
"Top Ten  
Greatest  
Inventions  
of 2008"



**Combat Gauze**



Borgman MA, et al, J Trauma. Oct 2007

↓ Mortality by ↑ Plasma:RBC Ratio



# Post 9/11 Fielded Products



**Hypothermia Prevention and Management Kit (HPMK)**



**Warrior Aid and Litter Kit (WALK)**



**Stand Alone Patient Simulator (METI - iSTAN)**



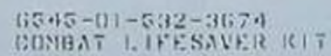
**Improved First Aid Kit (IFAK)**



**Combat Pill Pack**



**Golden Hour Container**



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# Combat Gauze™



**DESCRIPTION:** Combat Gauze™ is an advanced hemostatic agent combined with standard gauze bandage material. The active ingredient absorbs water from blood and promotes clot formation.

**REQUIREMENT:** FOC 09-06 Health Services Support 7 (d) Stabilize Casualty – naturally enhanced and synthetic materials to promote blood clotting, whether externally applied or injected into the body



**PARTNER:** Z-Medica Corporation

**TRANSITION:** Commercially available

**COST:** \$38.99

**QTY:**

**SCHEDULE:** Fielded. Issued one per soldier with the Individual First Aid Kit

# Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG)



**DESCRIPTION:** The RVPSAOG is designed to replace the "D" cylinder for patient care and transport. The RVPSAOG is a substantial simplification of existing pressure swing adsorption oxygen generator technology. The use of a rotary valve, driven directly by a small motor, eliminates complex valve and control systems used in conventional oxygen generators. Taking advantage of the reduced complexity reduces the weight and size of the oxygen generator and increases the efficiency of the generation process.

**REQUIREMENT:** The ambulance medical equipment set required oxygen bottles that could not be used because of the threat environment



**PARTNERS:** U.S. Army Medical Materiel Development Activity (USAMMDA), SeQual

**TRANSITION:** March 2008

**COST:** \$4,000

**QTY:** 1,500

**SCHEDULE:** Delivered

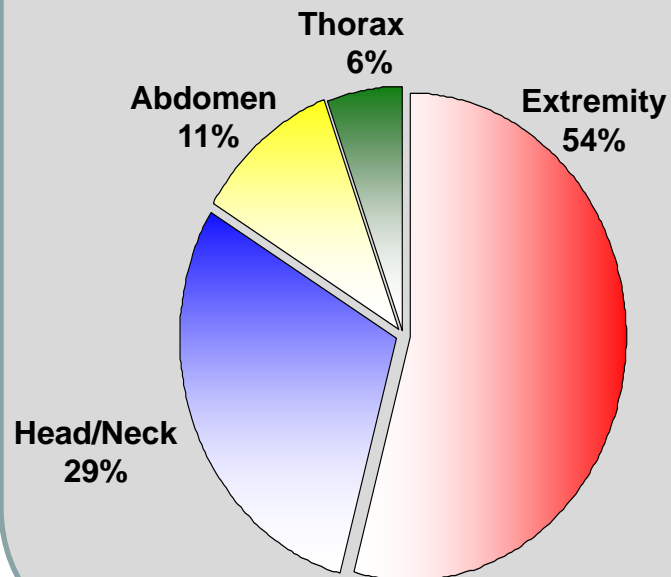


# EXTREMITY INJURIES



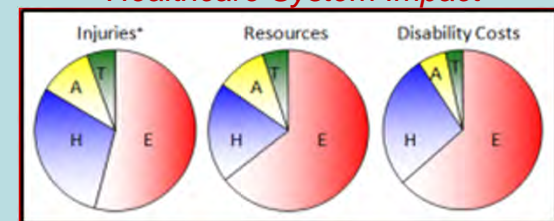
## Characterization of Extremity Wounds in Operation Iraqi Freedom and Operation Enduring Freedom

Brett D. Owens, MD, John F. Kragh, Jr, MD, Joseph Macaitis, BS, Steven J. Svoboda, MD, and Joseph C. Wenke, PhD  
(J Orthop Trauma 2007;21:254-257)



- 1,566 soldiers sustained 6,609 combat wounds
  - 4.2 wounds per soldier
- 3,575 extremity wounds
  - 82% of soldiers with at least one extremity wound
- 2.3 Extremity injuries/wounded soldier
- 1.3 OMF injuries/wounded soldier

### Healthcare System Impact

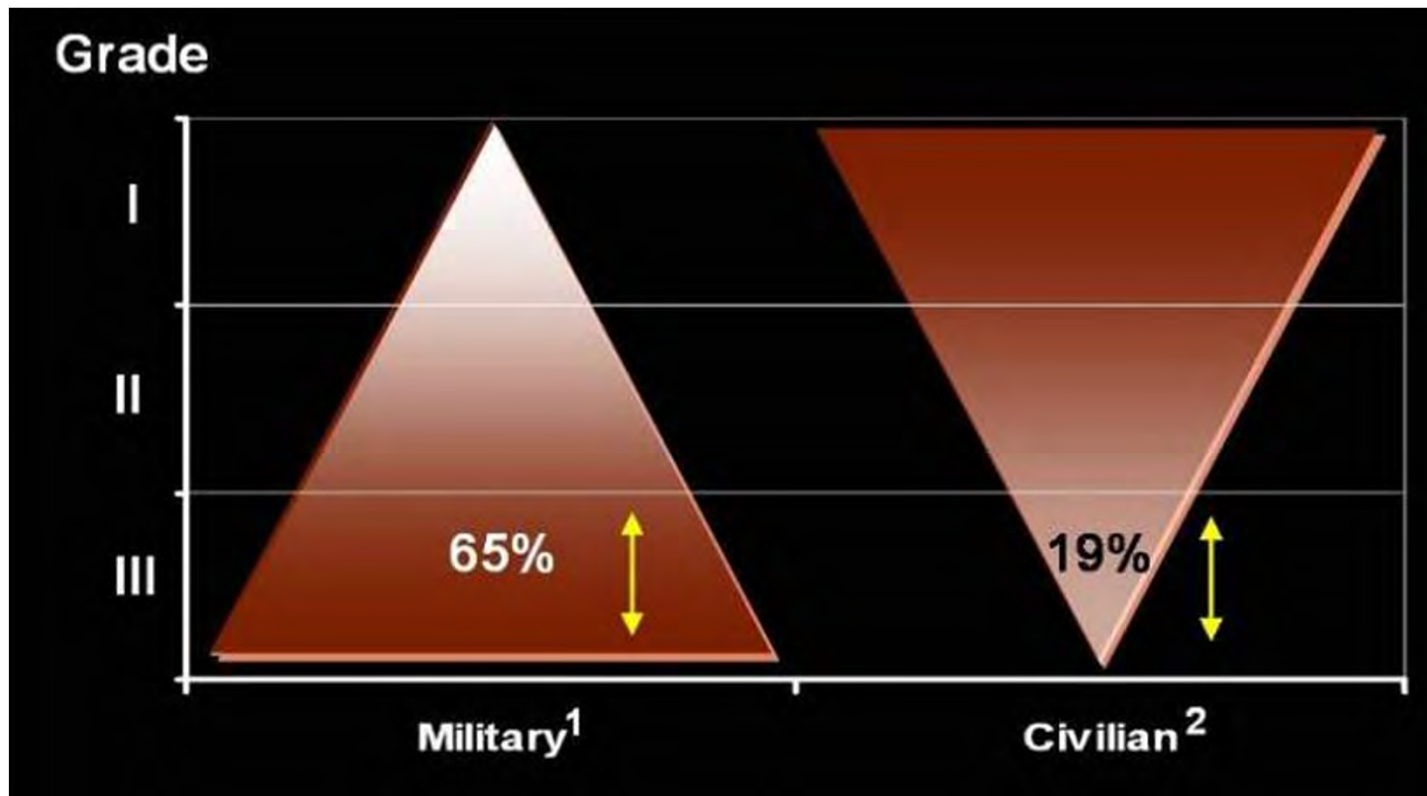


Submitted to Journal of Orthopaedic Trauma,  
accepted at AAOS annual meeting 2009

# EXTREMITY INJURIES



## *Injury Severity Relative to Civilian Medicine - Fractures*



<sup>1</sup>Johnson, Burns et al. 2007; <sup>2</sup>Gustilo and Anderson 2002



# Armed Forces Institute of Regenerative Medicine (AFIRM) Goal: To Heal our Wounded Warriors



## *Five Areas of Emphasis*



**1. Cranio-Facial Reconstruction**



**2. Healing Without Scarring**



**3. Limb and Digit Salvage and Reconstruction**



**4. Compartment Syndrome**

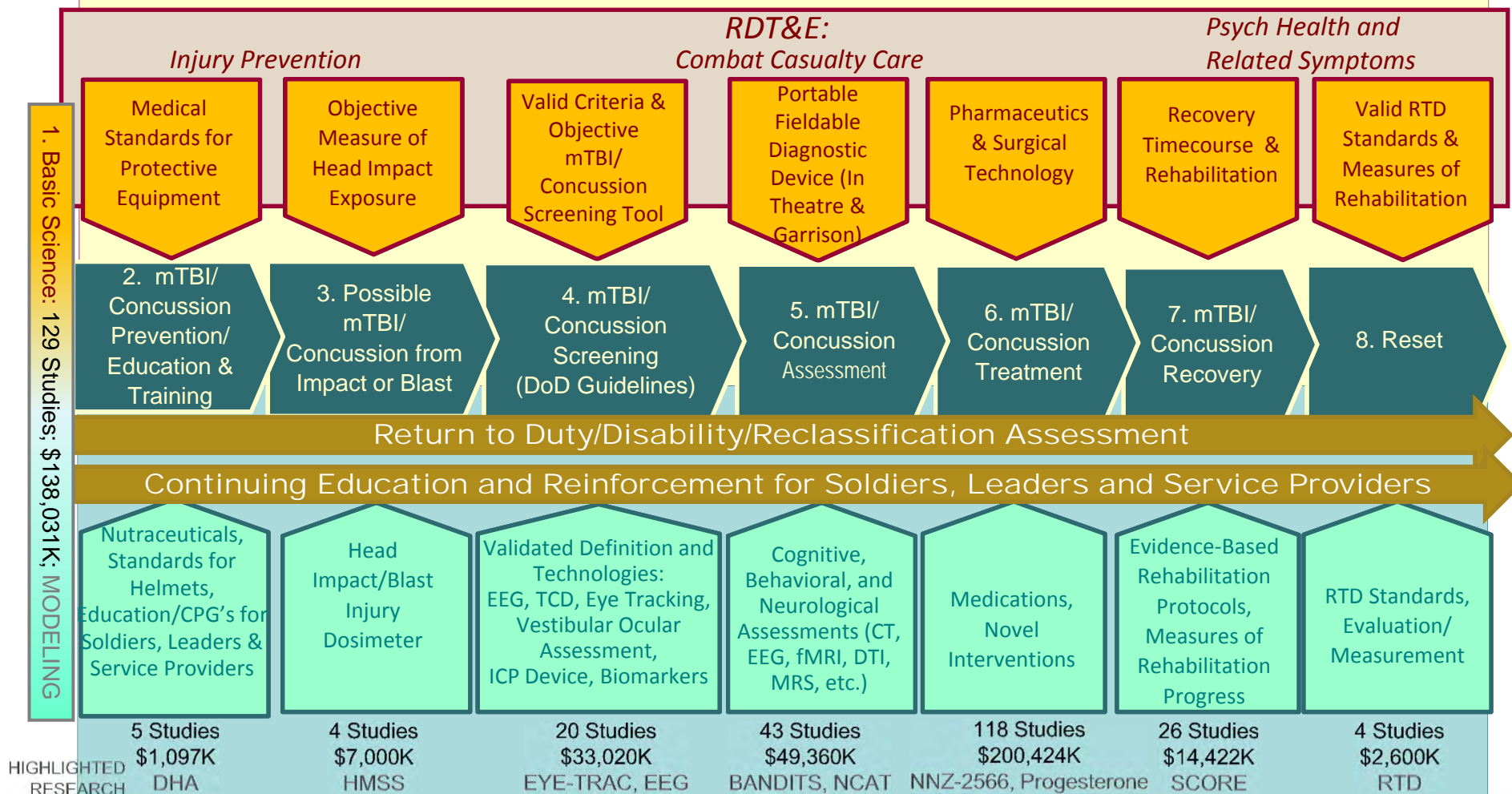


**5. Burn Repair**



# Continuum of TBI Care Determines Research Approach

## RESEARCH NEEDS



## SOLUTIONS



# 1. Basic Science



## *The Importance of Neurogenic Inflammation in Blast-Induced Neurotrauma*

PI: Cernak, Ibolja

Johns Hopkins University, Applied Physics Laboratory

\$1.132 m

1 Oct 2010 to 30 Sep 2013

### Aims

- Identify vital mechanisms of neurodegeneration initiated by blast exposure thus defining novel diagnostic and therapeutic targets

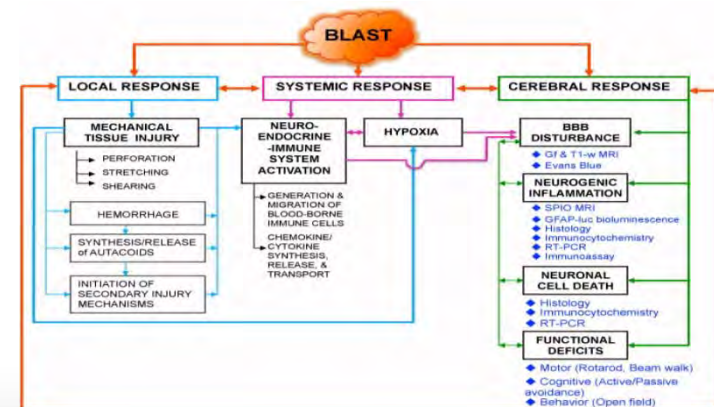
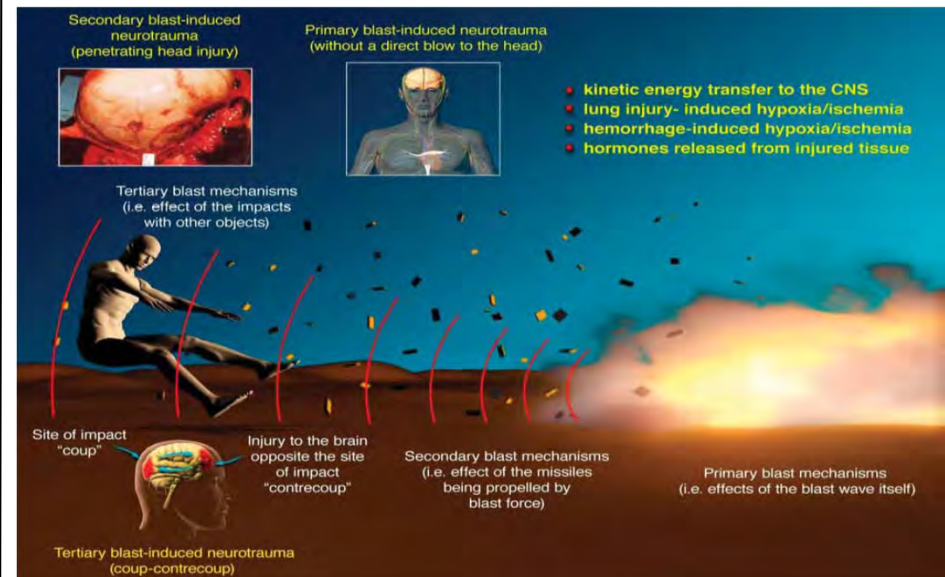
### Approach

- Military-relevant blast scenarios are being replicated in controlled laboratory conditions using a multichamber, compressed gas-driven shock tube
- Mice are being exposed to graded (low, moderate, or high) intensity shock waves
- Mice are being imaged using superparamagnetic iron-oxide particle (SPIO)-enhanced T2-weighted (T2-w) magnetic resonance imaging (MRI), gadofluorine-enhanced T1-weighted (T1-w) MRI, and manganese chloride-weighted MRI
- Mechanisms of inflammatory response are being measured by various means

### Deliverables

- Knowledge on brain inflammation due to blast and information on the importance of changes originating in the periphery on integrity

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## 2. TBI / Concussion Prevention and Protection



### *mTBI Prevention: Pharmaceutical for Neuroprotection and Resilience - DHA*

PI: COL Michael Lewis  
Defense Veterans and Brain Injury Center

\$1.0m  
Oct 2009-Oct 2011

MILESTONES	FY	11	12
Develop supplementation formulation and procedures; get approvals			
Conduct efficacy studies			
Dissemination of findings			

#### Aims/Approach

- Develop and evaluate efficacy of docosahexaenoic acid (DHA) for neuroprotection against negative consequences of blast exposures and improved recovery following blast exposure and/or traumatic brain injury
- Study comparing DHA versus placebo administration in a special operations unit with a high rate of blast exposure

#### Deliverables

- If effective, DHA may provide some degree of neuroprotection against negative consequences associated with blast exposures

#### Project Status

- DHA formulation is being redesigned to be more readily fieldable and feasible for special operations unit use
- Evaluation of DHA compared to placebo will be conducted once formulation is complete

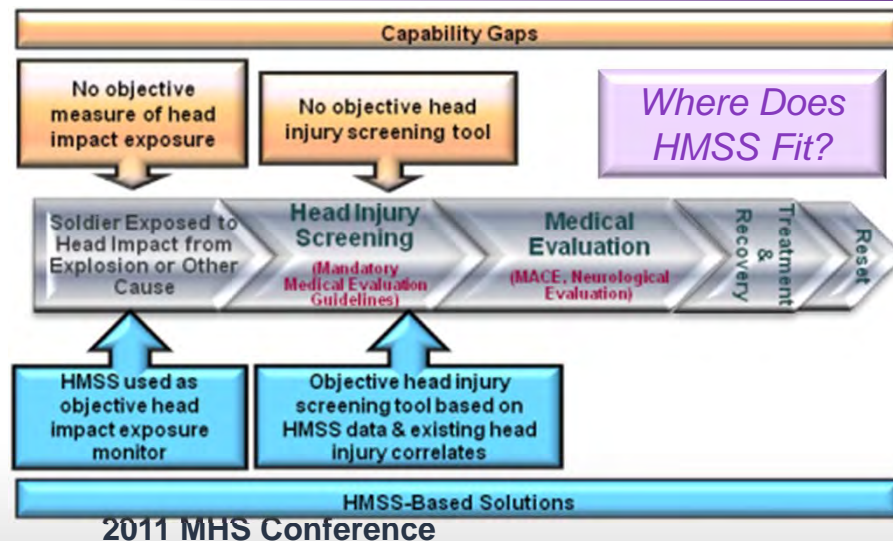
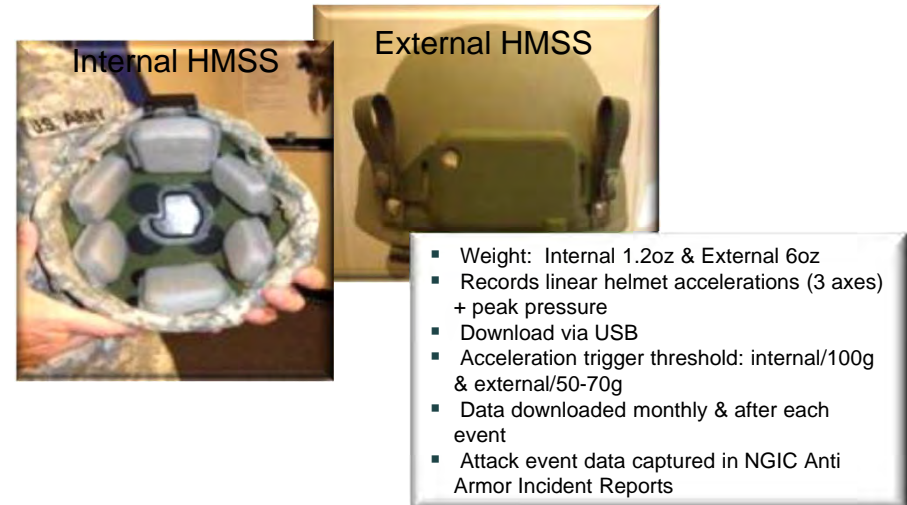


# 3. Objective Measure of Head Impact/ Blast Exposure



## Helmet Mounted Sensor System (HMSS)

- Army and Marine Corps fielded nearly 9,000 HMSS to deploying Soldiers and Marines
- Two versions fielded: Internal and External
- HMSS:
  - Recorded helmet acceleration & pressure from impacts/explosions
  - An exposure monitor, not a diagnostic tool
- Value of HMSS:
  - Monitor/document head impact exposures
  - Provide data for development of an objective head injury screening tool
  - Provide data for Next Generation Combat Helmet



- HMSS Data Analysis (Performers: USAARL, NHRC, and L-3/Jaycor [USAMRMC contract] with JTAPIC PMO lead )
  - Developed mathematical model that estimates acceleration-caused concussion “dose” using data from lab sensors. Identified HMSS performance problems and data artifacts
  - Developed data screening criteria and found ~60,000 of 250,000 HMSS recordings characteristic of blast/impact.
  - Determined there were too few HMSS and injury data matches to draw meaningful conclusions
    - Reasons: sensors that had incorrect starting dates, sensors that failed to record events, and unit compliance with sensor downloading requirements

# 4. Head Injury Screening



## ***EYE-TRAC: Eye-Tracking Device Objective Test for Post Concussion Syndrome***

PT075553

Eye-Tracking Rapid Attention Computation  
Brain Trauma Research Foundation

\$4,644 (\$K), PH/TBI CSI

15 Sep 2008 to 14 Oct 2012

### Aims

Develop a ruggedized eye-tracking device, EYE-TRAC, which has been proven to rapidly and accurately detect attention and memory deficiencies in civilian mild TBI

### Approach

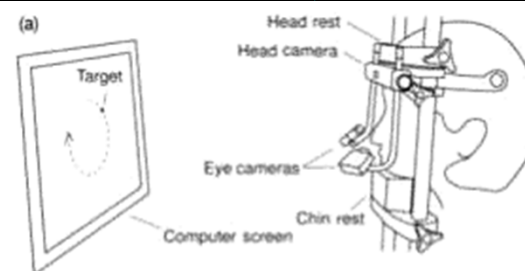
- Baseline measurements are being obtained in a large number of subjects to establish thresholds in different age groups and varying fatigue levels
- Validated standards that characterize attention deficits are being developed
- A prototype eye-tracking system is being built
- A battery of neurocognitive tests is being applied to test the EYE-TRAC device

### Deliverable

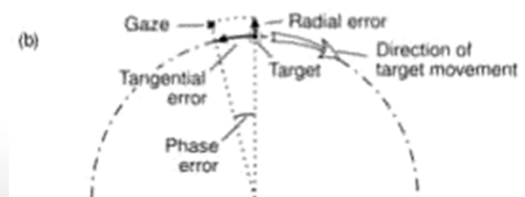
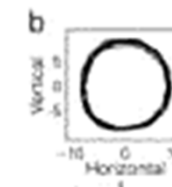
A portable, goggle-like prototype of an eye-tracking device for attention deficit assessment that distinguishes fatigue and PTSD from Post Concussion Syndrome

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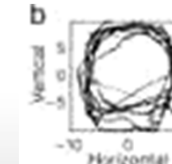
Milestones / FY	08	09	10	11	12	13
Collect EYE-TRAC data						
Develop test methods and appropriate software						
Ruggedize and build a prototype EYE-TRAC testing device						



Normal



PCS



# 4. Head Injury Screening



## Pre- and Post- Deployment Longitudinal Screening for Traumatic Brain Injury with a Hand-Held Real-Time Multichannel Algorithmic EEG Platform

PI: COL De Lorenzo, MD, Brooke Army Medical Center

### Problem, Hypothesis and Military Relevance

- Screening for TBI is cumbersome, requires provider training, and can lack objectivity
- A means to objectively and rapidly screen for TBI in deploying warfighters is needed.
- Emerging technology in portable, real-time algorithmic digital signal processed EEG system show promise.
- Proposal will study a new DSP-EEG device (Brainscope Ahead M-100) in a group of warfighters about to deploy and with follow-up on re-deployment home.
- Correlation of potential exposures, symptoms and diagnosis to changes in DSP-EEG results.

### Proposed Solution

- The device integrates DSP-EEG and computerized assessment to create a noninvasive, low-cost portable device:
  - Real-time, functional assessment at point of care
  - Non-invasive, painless and rapid
  - Portable, battery-operated for use anywhere
- Primary objective focuses on obtaining baseline data and comparing to post-deployment DSP-EEG, standardized neurocognitive testing, and follow-up.
  - A matched group of non-deploying warfighters will be recruited.
  - DSP-EEG changes within subjects and between groups will be analyzed.

Milestones/FY	11	12	13
IRB approval (min risk), Study run-in, subject enrollment			
Subject enrollment, deployment of group, gather exposure histories			
Re-deployment, acquire f/u data analysis, presentation, and publication			

## Brainscope Ahead M-100





# 5. Head Injury Assessment



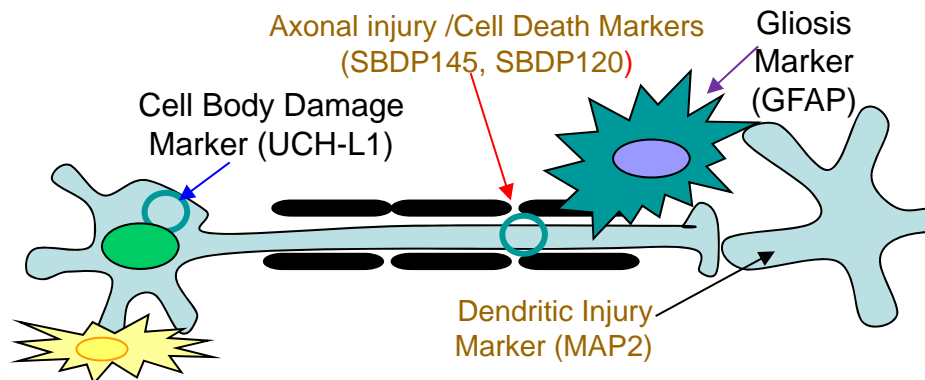
## *Biomarker Assessment for Neurotrauma Diagnosis & Improved Triage System (BANDITS)*

No test is currently approved to objectively diagnose TBI, particularly mTBI. The goal of the BANDITS program is to develop a blood test for brain cell damage, much like the current blood test (Troponin) for heart damage.

BANDITS will be embedded in an automated system available to Level III or lower echelons of care from a open benchtop system to a handheld device.

### GOALS

- Minimal- to non-invasive medical device to identify and assess internal brain injuries
- State-of-the-art lightweight, sturdy and reliable diagnostic systems appropriate for far forward screening, assessment, and care
- Designed to diagnose mild, moderate and severe traumatic brain injury



Benchtop System  
MedCent/CSH



POC System  
CSH/FST



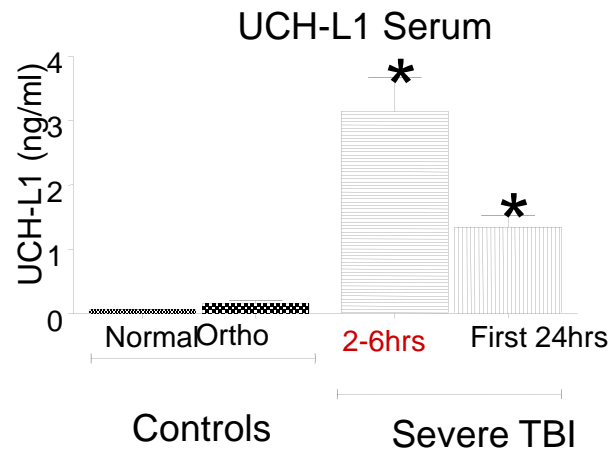
Handheld Device  
Combat Medic



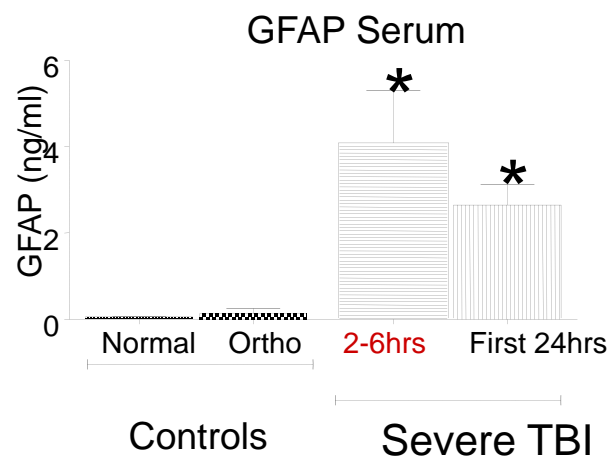


# BANDITS PROGRAM

## Biomarkers in Severe TBI Patients



UCH-L1 (Serum)	#	Mean	SEM	P value
Normal	176	0.06	0.004	
Ortho	11	0.16	1.04	
TBI 2-6 hrs	37	3.140	0.53	* <0.0001
TBI 24 hrs	101	1.35	0.18	* 0.0005



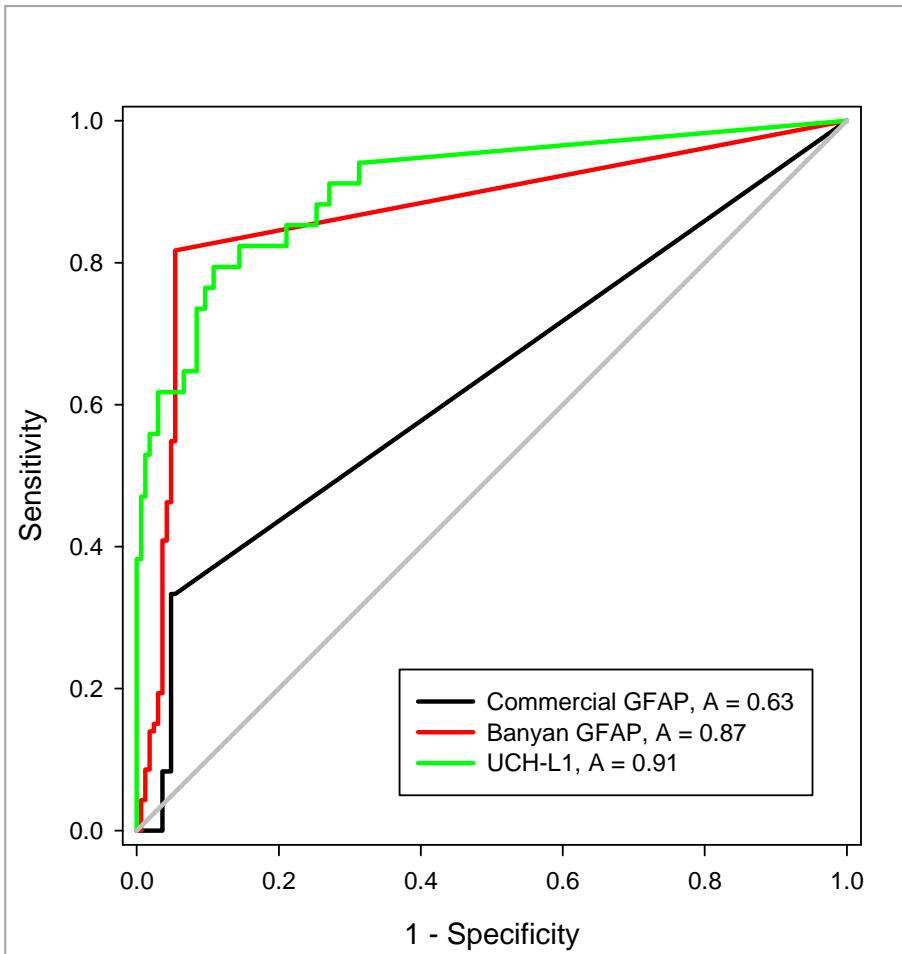
GFAP (Serum)	#	Mean	SEM	P value
Normal	176	0.06	0.008	
Ortho	11	0.13	0.13	
TBI 2-6 hrs	37	4.08	1.22	* <0.0001
TBI 24 hrs	101	2.65	0.49	* <0.0001

(p values of the Mann-Whitney test for differences between the groups [\*TBI versus Ortho Controls]).

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# BANDITS PROGRAM

## Biomarkers in Mild TBI Patients



	Commercial GFAP	Banyan GFAP	UCH-L1
ROC Curve Area	0.6328	0.8716	0.9072
Sample Size - TBI	34	34	34
Sample Size - Normal	166	166	166

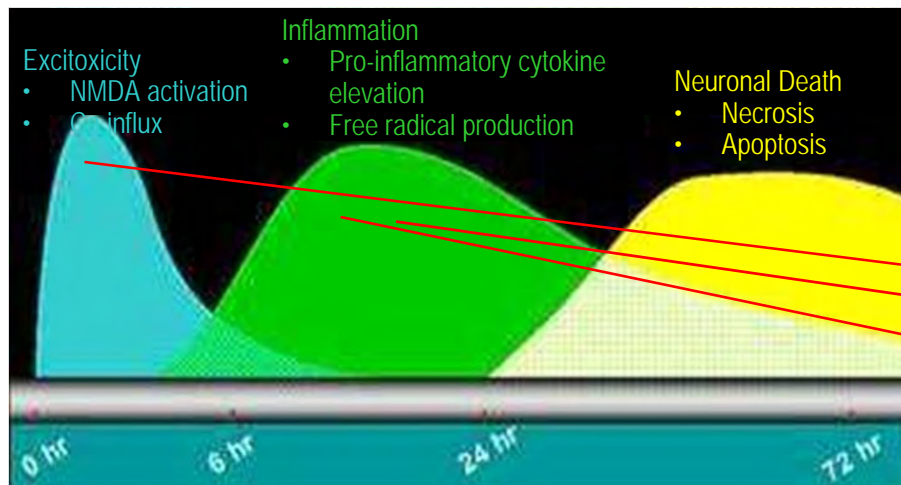
# 6. TBI / Concussion Treatment



## NNZ-2566 – Drug for Treatment of TBI

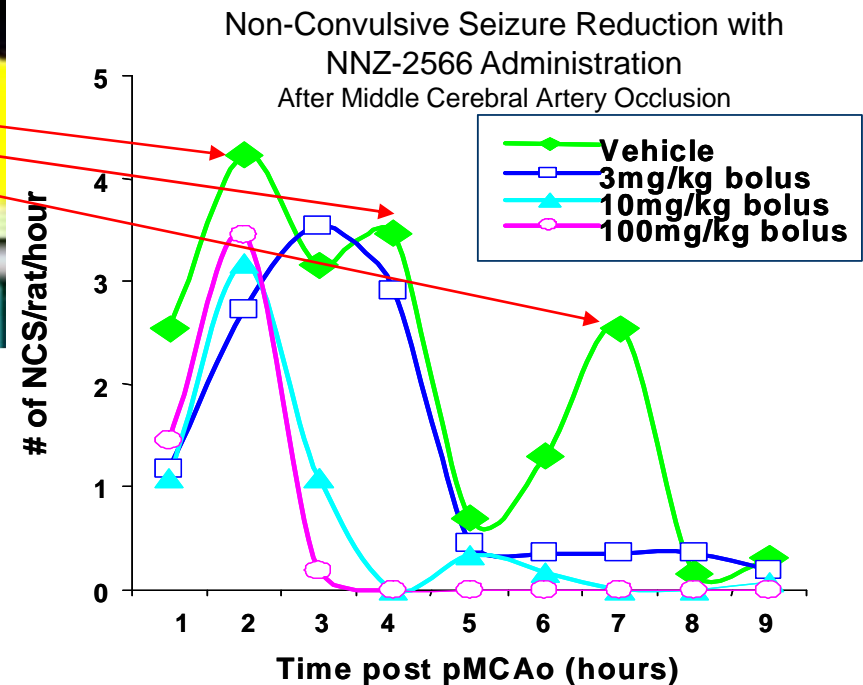
No effective treatment is approved for treating TBI, although multiple drugs have shown promise in preclinical tests.

- Other drugs in Phase II clinical trials include progesterone, growth hormone, erythropoietin, huperzine, pregnenalone, and atorvastatin, and others.



- NNZ-2566, a portion of the naturally occurring hormone, Insulin-like Growth Factor, has demonstrated a remarkable ability to reduce non-convulsive seizures in animal studies with TBI. Phase I safety studies have shown an excellent safety profile.
- A multicenter Phase II clinical trial in civilian TBI patients should be completed by the end of 2012.
- This clinical trial is unique in that it combines more than 15 biomarker and neurocognitive tests to assess functional outcome.
- NNZ-2566 has been formulated as a water-soluble IV form and an oral form.

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# 7. TBI / Concussion Recovery



## ***Study of Cognitive Rehabilitation Effects (SCORE):***

*A randomized treatment trial in a military population with mild traumatic brain injury incurred during deployment to OIF/OEF*

Director, Military Brain Injury Rehabilitation Research Consortium, SAMMC-N (Dr. Cooper)  
 Chief, Traumatic Brain Injury Service SAMMC-N (Dr. Bowles)  
 DVBIC ( Dr. Kennedy, COL Grimes, Dr. Vanderploeg)  
 WRAMC (Dr. French)  
 Jun 2010 – Dec 2013

Milestone/FY	10	11	12
Finalize research protocol			
Create Database			
Subject enrollment			
Data Analysis			
Dissemination			

### Aims/Approach

- Determine the effectiveness of cognitive rehabilitation in individuals with a history of mild TBI
- Determine which components of cognitive rehabilitation treatment (or combination of components) are most effective
- Determine which participant characteristics are associated with better treatment outcomes.
- Conduct an 18 week RCT investigating the effectiveness of cognitive rehabilitation on subjects with mild TBI
- Subjects will be randomly assigned to one of four treatment arms of the study: 1. Psycho-educational, 2. Self-administered computerized cognitive rehabilitation, 3. Therapist-directed individualized cognitive rehabilitation 4. Integrated interdisciplinary cognitive rehabilitation combined with cognitive behavioral psychotherapy.

### Deliverables

Empirically- validated cognitive rehabilitation interventions for service members with a history of mild TBI

### Project Status

- Steering committee workshop
- Scientific advisory review
- IRB Submission



# 8. TBI / Concussion Reset/RTD



## *TBI Return To Duty Assessment Tools*

US Army Aeromedical Research Laboratory  
(USAARL)  
(Catherine Webb; Thomas Harding; Angus Rupert)  
Abbott Northwestern Hospital MN  
(Mary Radomski)

\$2.6m  
Oct 2009-Sep 2012

MILESTONES	FY	09	10	11	12
Develop tools and operationalize procedures					
Validation studies					
Advanced development; dissemination of findings					

### Aims/Approach

- Develop objective repeatable assessments to aid RTD decisions following mTBI
- Weapon utilization tasks in conjunction with physiologic measures; battery of balance and vestibular tasks to aid RTD decisions
- Dual-task paradigm Combat readiness check (CRC) assessment which involves a highly familiar soldiering task with a second cognitive task to simulate operational demands and reveal safety-jeopardizing impairments

### Deliverables

- Cognitive, vestibular/oculomotor, and performance assessment tools to aid determination of readiness for RTD following mTBI

### Project Status

- Development of tools is underway and validation studies will be conducted
- Findings will inform test battery/measures improvement and standards for RTD decisions
- Establishing IPT and advanced development team to identify and transition most promising technologies



# Summary/Conclusion



- U.S. Trauma Research is largely the purview of the Department of Defense, as there is no Trauma Institute at the NIH, although trauma accounts for the largest loss in years of productive life
- Improvements in the medical care of battle casualties are being adopted by the civilian trauma system
- Recent increases in funding for military trauma funding are yielding important advances, particularly in hemorrhage control, brain injury diagnosis, and traumatic orthopedic injury
- There is a large backlog of clinical trials that need to be performed in trauma care